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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/618,545

07/11/2003

Anup Kumar Ray

G-33273P1

5175

1095

7590

08/24/2006

EXAMINER

ROGERS, JAMES WILLIAM

NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 08/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/618,545	RAY ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>07/12/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18 and 21-24 rejected under 35 U.S.C. 102(b) as being anticipated by Staub et al. (US 6,395,300 B1).

Staub teaches drug matrixes that can be processed into tablets or capsules comprising a drug (including paroxetine), a hydrophilic polymer (including PEG-8000), optionally a wetting agent (including TWEENTM 20, which is the same as polyoxyethylene(20)-sorbitanmonooleate), and several additional excipients, the weight ratio of PEG and the hydrophobic drug (prednisone) is within applicants specified range in the examples. See col 3 lin 1-9, col 7 lin 52, col 8 lin 10-65, col 8 lin 4-45, col 13 lin 38-46 and examples. Regarding the limitations on the melting point, the number of repeating units (n) and the average MW for PEG, these limitations are met because by the applicants disclosure PEG 800 has a MW 7000-9000 and a m.p. of 60-63 C°. Regarding claim 24 the limitation on the method of preparing is met because Staub teaches mixing PEG with the drug and surfactant and adding solvent and then drying the mixture.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staub et al. (US 6,395,300 B1) in view of Gibson et al. (US 5,811,120) and in view of Jacobs et al. (US 2003/0125391 A1).

Staub is disclosed above. Staub is silent on the exact methods of preparing a pharmaceutical composition as claimed in claims 25-26 and Staub is silent on the weight percent of surfactant used in the composition.

Gibson discloses an orally administrable Raloxifene formulation comprised of PEG-8000 and a sorbitan fatty acid ester as the surfactant. See abstract, col 3 lin 52-54,

col 5 lines 1-30 and examples. The amount of surfactant used in the examples meets the limitations on the weight percent of surfactant used in the compositions claimed by applicant. Also Gibson discloses methods to make the tablets in which a solution of the hydrophilic binder (could be PEG) and surfactant are added to a premix of drug and optionally a disintegrant and then dried.

Jacobs discloses pharmaceutical compositions containing modafinil, a carrier (including PEG-8000, PEG-4500 or PEG-1000) solvent and a surfactant (including TWEEN™ 20). See abstract, [0042]-[0043],[0048]. Jacobs also discloses methods for formulating tablets including a solvent method and a melt method; the melt method comprises adding modafinil compound to a melted carrier (PEG), cooling the mixture and milling to produce a powder for formulated tablets or capsules. See [0065]-[0068] and examples. Jacobs also incorporates a reference within, *J. Pharm Sci.* 1999, 88(10), 1058-1066, which details the melt method in more detail and discloses that the granules formed by the melt method were mixed with excipients.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Staub discloses all of applicants claimed invention but is silent on the exact amount of surfactant and the exact methods to form the pharmaceutical compositions as claimed, while Gibson disclosed the amount of surfactant in the same range of applicant as well as a method to make the tablet and Jacobs disclosed a melt method for forming a tablet. The motivation to combine the above documents would be a method to form a pharmaceutical composition comprising a hydrophobic drug, PEG and

Art Unit: 1618

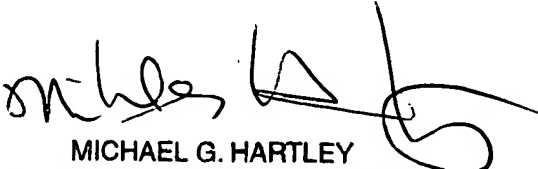
a surfactant, the methods can comprise wet granulation and then drying or a melt method in which the active is added to a melted PEG, milled and then mixed with an excipient. The benefit of the above composition would be a pharmaceutical composition having enhanced solubility comprising a drug and polyethylene glycol. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER